

Patent  
Attorney Docket:976626-100/001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: )  
)  
**DIXON, Gary S. et al.** )  
)  
**Serial No.:** 10/623,466 )  
)  
**Filed:** July 18, 2003 )  
)  
**For:** INTEGRATED PROTOCOL FOR )  
DIAGNOSIS, TREATMENT, AND )  
PREVENTION OF BONE MASS )  
DEGRADATION )

**Group Art Unit:** Not yet assigned

**Examiner:** Not yet assigned

**TRANSMITTAL**

Mail Stop DD  
Commissioner for Patents  
P.O. Box 1450  
Arlington, VA 22313-1450

Sir:

Transmitted herewith is the IDS Form 1449 for the above-identified application.

- ☐ Applicant(s) petitions for an extension of time under 37 CFR § 1.136 [fees: 37 CFR § 1.17(a)(1)-(5)] for the total number of months checked below:

<b>EXTENSION (months)</b>	<b>FEE FOR SMALL ENTITY</b>	<b>FEE FOR OTHER THAN SMALL ENTITY</b>
1 month	<input type="checkbox"/> \$55.00	<input type="checkbox"/> \$110.00
2 months	<input type="checkbox"/> \$210.00	<input type="checkbox"/> \$420.00
3 months	<input type="checkbox"/> \$475.00	<input type="checkbox"/> \$950.00
4 months	<input type="checkbox"/> \$740.00	<input type="checkbox"/> \$1,480.00

**CERTIFICATE OF MAILING**  
(37 C.F.R. § 1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, Washington, D.C., 20231.

December 18, 2003  
Date of Deposit  
LAI-2082081v1

Trisha Dolman  
Name of Person Mailing Paper

*Trisha Dolman*  
Signature of Person Mailing Document

- ☐ An extension for \_\_\_\_\_ months has already been secured and the fee paid therefor of \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.
- ☐ Extension fee due with this Request \_\_\_\_\_.
- ☐ If an additional extension of time is required, please consider this a petition therefor.

**FEES FOR CLAIMS:**

The fees for claims (37 CFR § 1.16(b)-(d)) have been calculated as shown below:

Total Claims	-	20	=	x	\$18.00	\$00.00
Independent Claims	-	3	=	x	\$84.00	\$00.00
Multiple Dependent Claims	\$280	(if applicable)			<input type="checkbox"/>	\$0.00
<b>TOTAL OF ABOVE CALCULATIONS</b>						\$00.00
Reduction by ½ for Filing by Small Entity. Note 37 CFR §§ 1.9, 1.27, 1.28.						\$0.00
<b>TOTAL FEES FOR CLAIMS SUBMITTED HEREWITH</b>						\$00.00

- ☐ A check in the amount of \$0.00 is enclosed to cover the above fee(s).
- ☐ Charge Jones Day Deposit Account No. **50-2468** in the amount of \$0.00.
- ☒ The Commissioner is authorized to charge Jones Day Deposit Account No. **50-2468** for any fees required under 37 CFR §§ 1.16 and 1.17 that are not covered, in whole or in part, by a check enclosed herewith and to credit any overpayments to said Deposit Account **50-2468**.

Respectfully submitted,

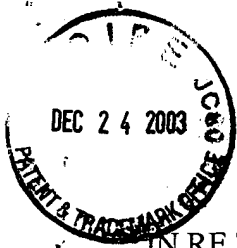
JONES DAY

Dated: December 18, 2003

By: \_\_\_\_\_

Charles C. Wong  
Reg. No. 50,423

555 West Fifth Street, Suite 4600  
Los Angeles, California 90013-1025  
(213) 243-2612



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE THE APPLICATION OF:

Dixon, Gary S. et al.

Serial No.: 10/623,466

Filed: July 18, 2003

For: INTEGRATED PROTOCOL FOR  
DIAGNOSIS, TREATMENT, AND  
PREVENTION OF BONE MASS  
DEGRADATION

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned.

INFORMATION DISCLOSURE STATEMENT

Mail Stop DD  
Commissioner for Patents  
P.O. Box 1450  
Arlington, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached Form PTO-1449 and copies are enclosed for the convenience of the Examiner.

The items identified in the IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

CERTIFICATE OF MAILING  
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Mail Stop DD, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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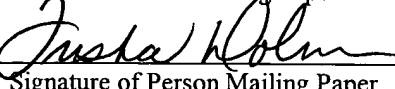
December 19, 2003

Date of Deposit

LAI-2072799v1

Trisha Dolman

Name of Person Mailing Paper



Signature of Person Mailing Paper

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

☒ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

☒ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider the IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.

☐ However, if the undersigned is in error in this regard, Applicant respectfully request that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

☐ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.

☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, the Applicant respectfully request that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

**STATEMENT UNDER 37 CFR § 1.97(e):**

☐ Each item contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.

☐ No item contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquire, no item of information contained in the IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

☐

A check in the amount of \_\_\_\_\_ is enclosed for the above fees(s).

☐

Please charge \_\_\_\_\_ to Deposit Account No. **50-2468** for the above fee(s).

☒

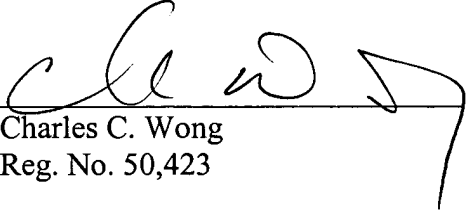
The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Jones Day Deposit Account No. **50-2468**.

Respectfully submitted,

JONES DAY

Dated: December 18, 2003

By: \_\_\_\_\_

  
Charles C. Wong  
Reg. No. 50,423

555 West Fifth Street, Suite 4600  
Los Angeles, California 90013-1025  
(213) 243-2317

FORM PTO-1449

ATTY. DOCKET NO.

976626-100/001

SERIAL NO.

10/623,466

**LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT**

APPLICANT:

Dixon, Gary S., et al.

FILING DATE:

July 18, 2003

GROUP:

Not yet assigned

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
AA	6,077,224	06/20/00	Lang, et al.			
AB	6,013,031	01/11/00	Mendlein, et al.			
AC	4,829,549	05/09/89	Vogel, et al.			
AD	6,090,046	07/18/00	Goll, et al.			
AE	5,218,963	06/15/93	Mazess			
AF	6,252,928	06/26/01	MacKenzie			
AG	5,917,877	06/29/99	Chiabrera et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES NO


## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

AH	AACE and the American College of Endocrinology, AACE clinical practice guidelines for the prevention and treatment of postmenopausal osteoporosis. <i>Endocr Pract.</i> 1996; 1:157-171.
AI	Anonymous. <i>Osteoporosis. Clinical Guidelines for Prevention and Treatment.</i> London: Royal College of Physicians, 1999.
AJ	Baran, D.T., Faulkner, K.G., Genant, H.K., et al. Diagnosis and management of osteoporosis: guidelines for the utilization of bone densitometry. <i>Calcif Tissue Int.</i> , 1997; 61:433-440.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant

<b>FORM PTO-1449</b> 	<b>ATTY. DOCKET NO.</b> 976626-100/001	<b>SERIAL NO.</b> 10/623,466
	<b>APPLICANT:</b> Dixon, Gary S., et al.	
	<b>FILING DATE:</b> July 18, 2003	<b>GROUP:</b> Not yet assigned

(Use several sheets if necessary)

AK	Baur, D.C., Gluer, C.C., Cauley, J.S. et al., Broadband ultrasound attenuation predicts fractures strongly and independently of densitometry in older women: a prospective study. <i>Archives of Internal Medicine</i> , 1997; 157:629-634.
AL	Bauer, D.C., Gluer, C.C., Genant, H.K., et al., Quantitative ultrasound and vertebral fracture in postmenopausal women, <i>J. Bone Miner Res.</i> , 1995; 10:353-358.
AM	Bikle, D.D., Biochemical markers in the assessment of bone disease. <i>Am J. Med.</i> 1997; 103:427-436.
AN	Black D.M., Cummings S.R., Genant H.K., et al. Axial and appendicular bone density predict fractures in older women. <i>J Bone Miner Res.</i> 1992;7:633-638.
AO	Blake G.M., Preston N.G., Patel R., Herd J.M., Fogelman I. Monitoring skeletal response to treatment: Which site to measure in the femur? <i>Journal of Clinical Densitometry</i> 2000; 3(2): 149-155.
AP	Bracker M.D., Watts N.B. How to get the most out of bone densitometry. <i>Postgrad Med/Densitometry.</i> 1998;104:77-86.
AQ	Cadarette S.M., Jaglal S.B., Kreiger N., McIsaac W.J., Darlington G.A., Tu J.V. Development and validation of the Osteoporosis Risk Assessment Instrument to facilitate selection of women for bone densitometry. <i>Canadian Medical Association Journal</i> 2000; 162(9): 1289-1294
AR	Chapurlat R.D., Garnero P., Breart G., Meunier P.J., Delmas P.D. Serum type I collagen breakdown product (serum CTX) predicts hip fracture risk in elderly women: the EPIDOS study. <i>Bone</i> 2000; 27(2): 283-286.
AS	Chen Z, Maricic M, Lund P, Tesser J, Gluck O. How the new Hologic hip normal reference values affect the densitometric diagnosis of osteoporosis. <i>Osteoporosis</i> 1998; 8: 423-489.
AT	Dargent-Molina P., Favier F., Grandjean H., et al. Fall-related factors and risk of hip fracture : the EPIDOS prospective study. <i>Lancet</i> 1996; 348: 145-149.
AU	Delmas P.D., Garnero P. Utility of biochemical markers of bone turnover in osteoporosis. In: Marcus R, Feldman D, Kelsey J. <i>Osteoporosis</i> . San Diego, Calif: Academic Press; 1996:1075-1088.
AV	Delmas P.D., Eastell R., Garnero P., Seibel M.J., Stepan J., for the Committee of Scientific Advisors of the International Osteoporosis Foundation. The use of biochemical markers of bone turnover in osteoporosis. <i>Osteoporosis International</i> 2000; suppl.6: S2-S17.
AW	Eddy D.M., Johnston C.C., Cummings S.R., et al. Osteoporosis: Review of the evidence for prevention, diagnosis and treatment and cost-effectiveness analysis. <i>Osteoporosis International</i> 1998; 8(suppl.4): S1-S88.
AX	Faulkner K., Miller P., Siris E., et al. Difference in BMD across skeletal sites: evidence from the specialist arm of the National Osteoporosis Risk Assessment (NORA). <i>J Bone Miner Res.</i> 1999;14(suppl. 1):S200.
AY	Frost M.L., Blake G.M., Fogelman I. Can the WHO criteria for diagnosing osteoporosis be applied to calcaneal quantitative ultrasound? <i>Osteoporosis International</i> 2000; 11: 321-330.

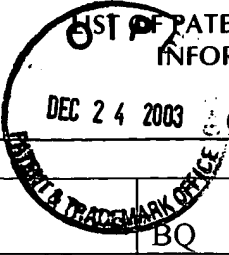
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<b>LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)	APPLICANT: Dixon, Gary S., et al.	
	FILING DATE: July 18, 2003	GROUP: Not yet assigned

		Garnero P., Hausherr E., Chapuy M.C., et al. Markers of bone resorption predict hip fracture in elderly women: The EPIDOS Prospective Study. <i>J Bone Miner Res.</i> 1996;11:1531-1538.
	BA	Garnero P., Delmas P.D. New developments in biochemical markers for osteoporosis. <i>Calcif Tissue Int.</i> 1996;59(Suppl 1): S2-S9.
	BB	Garnero P., Shih W.J., Gineyts E., et al. Comparison of new biochemical markers of bone turnover in late postmenopausal osteoporotic women in response to alendronate treatment. <i>J Clin Endocrinol Metab.</i> 1994;79:1693-1700.
	BC	Genant H.K., Cooper C., Poor G. Interim report and recommendations of the World Health Organisation Task-Force for osteoporosis. Short report. <i>Osteoporosis International</i> 1999; 10(4) 259-264.
	BD	Greenspan S.L., Bouxsein M.L., Melton M.E., et al. Precision and discriminatory ability of calcaneal bone assessment technologies. <i>J Bone Miner Res.</i> 1997;12:1303-1313.
	BE	Hans D., Dargent-Molina P., Schott A.M., et al. Ultrasonographic heel measurements to predict hip fracture in elderly women: the EPIDOS prospective study. <i>Lancet.</i> 1996;348:511-514.
	BF	Jergas M., Genant H.K. Current methods and recent advances in the diagnosis of osteoporosis. <i>Arthritis Rheum.</i> 1993;12:1649-1662.
	BG	Kanis J.A. Assessment of bone mass and osteoporosis. In: <i>Osteoporosis</i> . Oxford, England: Blackwell Science, Ltd; 1994:114-147.
	BH	Kanis J.A., Gluer C.C. An update on the diagnosis and assessment of osteoporosis with densitometry. <i>Osteoporosis International</i> 2000; 11: 192-202.
	BI	Kanis J.A., Delmas P., Buckhardt P., Cooper C., Torgerson D., on behalf of the European Foundation for Osteoporosis and Bone Disease. Guidelines for diagnosis and management of osteoporosis. <i>Osteoporosis International</i> 1997; 7: 390-406
	BJ	Kelly T.L., Crane G., Baran D.T., et al. Single X-ray absorptiometry of the forearm: precision, correlation, and reference data. <i>Calcif Tissue Int.</i> 1994;54:212-218.
	BK	Kleerekoper M. Detecting osteoporosis: beyond the history and physical examination. <i>Postgrad Med/Osteoporosis.</i> 1998;103:45-68.
	BL	Levinson W., Altkorn D. Primary prevention of postmenopausal osteoporosis. <i>JAMA.</i> 1998;280:1821-1822.
	BM	Levis S., Altman R. Bone densitometry: clinical considerations. <i>Arthritis Rheum.</i> 1998;41:577-587.
	BN	Lydick E., Cook K., Turpin J., et al. Development and validation of a simple questionnaire to facilitate identification of women likely to have low bone density. <i>Am J Man Care.</i> 1998;4:37-48.
	BO	Marshall D., Johnell O., Wedel H. Meta-analysis of how well measures of bone mineral density predict occurrence of osteoporotic fractures. <i>British Medical Journal</i> 1996; 312: 1254-1259.
	BP	Melton L.J. III, Atkinson E.J., O'Fallon W.M., et al. Long-term fracture prediction by bone mineral assessed at different skeletal sites. <i>J Bone Miner Res.</i> 1993;8:1227-1233.

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<b>FORM PTO-1449</b>  <b>PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)	<b>ATTY. DOCKET NO.</b> 976626-100/001	<b>SERIAL NO.</b> 10/623,466
	<b>APPLICANT:</b> Dixon, Gary S., et al.	
	<b>FILING DATE:</b> July 18, 2003	<b>GROUP:</b> Not yet assigned

BQ	Miller P.D., Baran D.T., Bilezikian J.P., et al. Practical clinical application of biochemical markers of bone turnover: consensus of an expert panel. <i>J Clin Densitometry</i> . 1999;2:323-342.
BR	Miller P.D., Bonnick S.L., Johnston C.C. Jr., et al. The challenges of peripheral bone density testing. <i>J Clin Densitometry</i> . 1998;1:211-217.
BS	National Osteoporosis Foundation. <i>Physician's Guide to Prevention and Treatment of Osteoporosis</i> . Washington D.C.: National Osteoporosis Foundations; 1998.
BT	National Osteoporosis Foundation. Osteoporosis: review of the evidence for prevention, diagnosis, and treatment and cost-effectiveness analysis. Status Report. <i>Osteoporosis Int</i> . 1998;(suppl. 4): S1-S82.
BU	Nordin BEC. Guidelines for bone densitometry. <i>Med J Aust</i> . 1994;160:517-520.
BV	Pluijm S.M.F., Graafmans W.C., Bouter L.M., Lips P. Ultrasound measurement for the prediction of osteoporotic fractures in elderly people. <i>Osteoporosis International</i> 1999; 9: 550-556.
BW	Prins S.H., Jorgensen H.L., Jorgensen L.V., Hassager C. The role of quantitative ultrasound in the assessment of bone: a review. <i>Clinical Physiology</i> 1998; 18(1): 3-17.
BX	Riggs B.L., Wahner H.W., Dunn W.L., et al. Differential changes in bone mineral density of the appendicular and axial skeleton with aging: Relationship to spinal osteoporosis. <i>J Clin Invest</i> 1981;67:328-335.
BY	Ringertz H., Marshall D., Johannsson C. et al. Bone Density Measurement - A Systematic Review. <i>Journal of Internal Medicine</i> 1997; 241(suppl 739): 1 - 60
BZ	Robins S.P., Woitge H., Hesley R., et al. Direct, enzyme-linked immunoassay for urinary deoxypyridinoline as a specific marker for measuring bone resorption. <i>J Bone Miner Res</i> . 1994;9:1643-1649.
CA	Rowe R. The management of osteoporosis in general practice: Results of a National Survey. <i>Osteoporosis Review</i> 1999; 7: 1-3
CB	Seyedin S.M., Kung V.T., Daniloff Y.N., et al. Immunoassay for urinary pyridinoline: the new marker of bone resorption. <i>J Bone Miner Res</i> . 1993;8:635-641.
CC	Sim M.F., Stone M., Johansen A., Evans W. Cost effectiveness analysis of BMD referral for DXA using ultrasound as a selective pre-screen in a group of women with low trauma Colles' fractures. <i>Technology &amp; Health Care</i> 2000; 8(5): 277-284.
CD	Sinaki M., Mikkelsen B.A. Postmenopausal spinal osteoporosis; flexion versus extension exercises. <i>Arch Phys Med Rehabil</i> . 1984;65:593-596.
CE	Wahner H.W., Steiger P., von Stetten E. Instruments and measurements techniques. In: Wahner H.W., Fogelman I. <i>The Evaluation of Osteoporosis: Dual Energy X-ray Absorptiometry in Clinical Practice</i> . London, England: Martin Dunitz; 1994:14-34.
CF	World Health Organisation. <i>Assessment of Fracture Risk and its Application to Screening for Postmenopausal Osteoporosis</i> . WHO Technical Report Series 843. Geneva: WHO, 1994

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